

The Honorable Thomas S. Zilly

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE**

PROTEOTECH, INC., a Washington Corporation and UNIVERSITY OF WASHINGTON, a public institution of higher learning,)) No. CV6-1297Z
Plaintiffs,)) JOINT CLAIM CONSTRUCTION CHARTS
v.)
UNICITY INTERNATIONAL, INC., a Utah corporation,)
Defendant.)
UNICITY INTERNATIONAL, INC., a Delaware corporation,)
Third-Party Plaintiff,)
v.)
NBTY, INC., a Delaware corporation,)
Third-Party Defendant.)

Pursuant to the Court's Minute Order Setting Trial and Related Dates issued December 8, 2006, Plaintiff ProteoTech, Inc. ("Plaintiff ProteoTech") and Defendant Unicity International, Inc. ("Defendant Unicity") hereby submit two Joint Claim Construction Charts. One term is in dispute: "therapeutically effective amount," found in U.S. Patent No. 6,939,570 in claims 1, 2, 4, 5, 8 – 11, and 14. The parties agree on the

1 additional definitions set forth in the Joint Claim Charts.

2 Copies of U.S. Patent Nos. 6,264,994 and 6,939,570 are attached hereto as Exhibits
 3 A and B respectively. As the Joint Claim Chart contains no citations to the patents'
 4 respective prosecution histories, no portions of those prosecution histories are attached.
 5 The parties have the complete prosecution history for each of the patents at issue available
 6 at the Court's request.

8 JOINT CLAIM CONSTRUCTION CHART '994 PATENT

9 Claim Language	10 Plaintiff's Proposed Construction and Evidence 11 in Support	12 Defendant's 13 Proposed 14 Construction and 15 Evidence in Support
16 Term 1. A composition 17 comprising plant 18 matter from . . . 19 Found in claim numbers 20 1 - 4, 6, 10 - 14, and 17.	21 plant matter <u>Proposed Construction:</u> 22 "Any substance taken from a member of the 23 plant kingdom including the plant itself as well 24 as extracts and derivatives thereof." <u>Dictionary / Treatise Definitions:</u> 25 THE MERRIAM-WEBSTER DICTIONARY, NEW 26 EDITION (Frederick C. Mish ed., 1994) 27 matter: "a specific type of substance (e.g., organic matter)." plant: "any of a kingdom of living things that usually have no locomotor ability or obvious sense organs and have cellulose cell walls and usually capacity for indefinite growth." <u>Intrinsic Evidence:</u> The opening sentence of the '994 Patent abstract states broadly that the invention is a "composition of plant matter comprising Uncaria tomentosa and at least one of ginkgo biloba, rosemary, gotu kola and bacopin." Abstract to '994 Patent Examples of plant matter described in the '994 Patent include inner bark and roots from cat's claw and leaves from gingko biloba. "Another	28 Agreed.

	<p>object of the present invention is to use the inner bark and/or roots from <i>Uncaria tomentosa</i> . . . for . . . treatment . . .” ‘994 Patent col. 2:10. Claim 2 of the ‘994 Patent includes “an extract obtained from the leaves of <i>gingko biloba</i>.”</p> <p>Another portion of the specification states that “the <i>plant matter</i> is preferably comprised of commercially obtained pills, tablets, caplets, soft and hard gelatin capsules, lozenges, sachets, cachets, vegicaps, liquid drops, elixers, suspensions, emulsions, solutions, syrups, tea bags, aerosols (as a solid or in a liquid medium), suppositories, sterile injectable solutions, sterile packaged powders, bark bundles and/or bark powder, which contain <i>Uncaria tomentosa</i>, extracts or derivatives thereof, and may be taken from commercially available gelatin-coated capsules which contain dried-powder of <i>Uncaria tomentosa</i>, extracts or derivatives thereof.” ‘994 Patent col. 10:5 (emphasis added).</p>	
<p>Term 2. . . . wherein the plant matter comprises an extract obtained from . . .</p> <p>Found in claim numbers 2, 6, and 10.</p>	<p>extract</p> <p><u>Proposed Construction:</u> “Something separated or otherwise obtained (as constituent elements or juices) from a substance, such as, by treating with a solvent (as alcohol), distilling, evaporating, subjecting to pressure or centrifugal force, or by some chemical, mechanical, or other extraction process.”</p> <p><u>Dictionary / Treatise Definitions:</u> WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (Phillip Babcock Gove, Ph.D. ed., 1993)</p> <p>extract (as a noun): “something extracted”</p> <p>extract (as a verb): “to separate or otherwise obtain (as constituent elements or juices) from a substance by treating with a solvent (as alcohol), distilling, evaporating, subjecting to pressure or centrifugal force, or by some other chemical or mechanical process.”</p> <p><u>Intrinsic Evidence:</u> In describing some of the different sources for obtaining cat’s claw, the patent specification refers to “<i>Uncaria tomentosa</i> extracted from different commercial sources (<i>extracts</i> isolated</p>	<p>Agreed.</p>

JOINT CLAIM CONSTRUCTION CHARTS (CV6-1297Z) — 3

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	<p>from gelatin-coated capsules, caplets or liquid form) were all found to serve as potent inhibitors of Alzheimer's disease amyloid fibrillogenesis." '994 Patent col. 6:30. Here, "extract" refers to the material separated from previously manufactured products that contain cat's claw.</p> <p>The specification also refers to "extract" as the resulting substance following a chemical process to break down the plant matter: "Another aspect of the invention is a method for isolating amyloid inhibitory constituents within Uncaria tomentosa plant matter, the method comprising the following steps: a) extracting the plant matter with an organic solvent, b) concentrating the extract, c) removing insoluble materials, d) precipitating amyloid inhibitory constituents with organic solvent e) recovering and redissolving the amyloid inhibitory constituents obtained in organic solvent, and f) injecting and separation by HPLC." '994 Patent col. 9:65 (emphasis added).</p> <p>The patent specification also describes the physical process of boiling to obtain the medicinal components of the cat's claw plant: "The native Indian tribes traditionally have boiled the inner bark and root of the herb to make a tea decoction and regard Uncaria tomentosa as a sacred medicinal plant. . . . The alkaloids and phytochemicals in the inner bark of Uncaria tomentosa are almost identical to those found in the root . . ." '994 Patent col. 17:5.</p>	
<p>Term 3. ... plant matter from the plant commonly known as cat's claw . . .</p> <p>Found in claims 1-4, 6, and 10-13.</p>	<p>cat's claw</p> <p><u>Proposed Construction:</u> "Those species of the genus Uncaria that are commonly known as cat's claw, including Uncaria tomentosa."</p> <p><u>Intrinsic Evidence:</u> "Uncaria tomentosa or Cat's claw is also referred to as, but not limited to, Paraguayo, Garabato, Garbato casha, Tambor huasca, Una de gavilan, Hawk's claw, Nail of Cat, and Nail of Cat Schuler." '994 Patent col. 2:15</p> <p>The specification is broader than Uncaria</p>	<p>Agreed.</p>

JOINT CLAIM CONSTRUCTION CHARTS
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	<p>tomentosa, however. "Another object of the present invention is to use extracts and/or derivatives thereof from plant matter related to the various Uncaria species, which may include but not limited to, Uncaria tomentosa, Uncaria attenuata, Uncaria elliptica, Uncaria guianensis, Uncaria pteropoda, Uncaria bernaysli, Uncaria ferra DC, Uncaria kawakamii, Uncaria rhyncophylla, Uncaria calophylla, Uncaria gambir, and Uncaria orientalis." '994 Patent col. 2:25.</p> <p>Similarly, "[w]hile results are exemplified with Species tomentosa, other species of Uncaria are believed to have similar effect." '994 Patent col. 6:35.</p>	
Terms 4 - 7. . . and plant matter selected from the group of plants consisting of, and commonly known as, ginkgo biloba , rosemary , gotu kola and bacopin . Found in claims 1-4, 6, and 10-13.	ginkgo biloba rosemary gotu kola bacopin <u>Proposed Construction:</u> These terms refer to herbal plants commonly used throughout the nutraceutical industry.	Agreed.
Term 8. . . an extract obtained from the inner bark of cat's claw . . . Found in claims 2, 6, and 10.	inner bark <u>Proposed Construction:</u> "That portion of the bark that lies closest to the center of the plant." <u>Dictionary / Treatise Definitions:</u> WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (Phillip Babcock Gove, Ph.D. ed., 1993) inner: "situated farther in <an inner chamber> <the inner bark>" bark: "the exterior dead cellular covering of woody roots and stems . . ."	Agreed.
Term 9. . . an amount of plant matter that has an in vitro amyloid inhibitory activity or efficacy	<u>Proposed Construction:</u> "Having the effect of reducing, suppressing,	Agreed.

JOINT CLAIM CONSTRUCTION CHARTS
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1 efficacy greater than 20%.	retarding, eliminating, preventing, inhibiting, interfering with, disrupting, and/or dissolving amyloid fibril or amyloid protein deposits.”	
2 Found in claim 17.	<p><u>Dictionary / Treatise Definitions:</u></p> <p>WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (Phillip Babcock Gove, Ph.D. ed., 1993)</p>	
3 inhibitory: “tending or serving to inhibit”	5 inhibitory: “tending or serving to inhibit”	
4 inhibit: “to reduce or suppress the activity of; to retard or prevent the formation of; to retard, interfere with, or prevent (a chemical process or reaction)”	7 inhibit: “to reduce or suppress the activity of; to retard or prevent the formation of; to retard, interfere with, or prevent (a chemical process or reaction)”	
5 efficacy: “the power to produce an effect”	8 efficacy: “the power to produce an effect”	
6 <u>Intrinsic Evidence:</u>	9 <u>Intrinsic Evidence:</u>	
7 The phrase relates to a measurement of the effectiveness of <i>Uncaria tomentosa</i> extract in inhibiting the formation or growth of amyloid deposits in laboratory test specimens. The efficacy of a substance in inhibiting amyloid formation can be measured through controlled bioassays. Some of these tests utilize Thioflavin T fluorometry. Thioflavin T is known to bind to fibrillar amyloid proteins, and an increase in fluorescence correlates with an increase in amyloid fibril formation, whereas a decrease in fluorescence correlates with a decrease in amyloid fibril formation. ‘994 Patent col. 20:45. In these tests, the effectiveness of the compound can be quantified by a reduction in fluorescence from the control group. For example, Figure 1 shows that after one week, the candidate labeled PTI-00700 reduced the fluorescence of Thioflavin T by 78% compared to the control group labeled AB. ‘994 Patent col. 22:5 and Figure 1.	10 The phrase relates to a measurement of the effectiveness of <i>Uncaria tomentosa</i> extract in inhibiting the formation or growth of amyloid deposits in laboratory test specimens. The efficacy of a substance in inhibiting amyloid formation can be measured through controlled bioassays. Some of these tests utilize Thioflavin T fluorometry. Thioflavin T is known to bind to fibrillar amyloid proteins, and an increase in fluorescence correlates with an increase in amyloid fibril formation, whereas a decrease in fluorescence correlates with a decrease in amyloid fibril formation. ‘994 Patent col. 20:45. In these tests, the effectiveness of the compound can be quantified by a reduction in fluorescence from the control group. For example, Figure 1 shows that after one week, the candidate labeled PTI-00700 reduced the fluorescence of Thioflavin T by 78% compared to the control group labeled AB. ‘994 Patent col. 22:5 and Figure 1.	
8 The specification also describes the effect of the patented composition. “Compositions of the invention, as formulated above, also have the ability to reduce, eliminate, prevent, inhibit or disrupt/dissolve amyloid fibril or protein deposits, brain associated amyloid fibril deposits or brain associated amyloid protein deposits, as well as amyloid fibril formation and growth or age associated amyloid fibril formation and growth, brain associated amyloid fibril	11 The specification also describes the effect of the patented composition. “Compositions of the invention, as formulated above, also have the ability to reduce, eliminate, prevent, inhibit or disrupt/dissolve amyloid fibril or protein deposits, brain associated amyloid fibril deposits or brain associated amyloid protein deposits, as well as amyloid fibril formation and growth or age associated amyloid fibril formation and growth, brain associated amyloid fibril	
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27	12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27	

1	formation and growth, and interaction of amyloid protein with glycosaminoglycans, or with proteoglycans.” ‘994 Patent col. 9:25.	
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JOINT CLAIM CONSTRUCTION CHART ‘570 PATENT

Claim Language	Plaintiff's Proposed Construction and Evidence in Support	Defendant's Proposed Construction and Evidence in Support
<p>Term 1. A pharmaceutical agent for treating an amyloid disease . . .</p> <p>Found in claims 1-14.</p>	<p>pharmaceutical agent</p> <p><u>Proposed Construction:</u> “A substance capable of producing a medicinal or therapeutic effect.”</p> <p><u>Dictionary / Treatise Definitions:</u> WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (Phillip Babcock Gove, Ph.D., ed., 1993)</p> <p>THE MERRIAM-WEBSTER DICTIONARY, NEW EDITION (Frederick C. Mish ed., 1994)</p> <p>pharmaceutical: “of, relating to, or engaged in pharmacy or the manufacture and sale of medicinal drugs.” MERRIAM-WEBSTER.</p> <p>pharmacy: “the art or practice of preparing, preserving, compounding and dispensing drugs, of discovering new drugs through research, and of synthesizing organic compounds of therapeutic value.” WEBSTER’S.</p> <p>agent: “means” or “instrument” (MERRIAM-WEBSTER) or more specifically, “a substance capable of producing a chemical reaction or a physical or biological effect.” WEBSTER’S.</p> <p><u>Intrinsic Evidence:</u> The opening sentence of the ‘570 Patent abstract states that the invention relates to compositions and methods for treating Alzheimer’s disease. ‘570 Patent Abstract.</p>	<p>Agreed.</p>

1	And, throughout the '570 Patent, the specification refers to the treatment of amyloid diseases. Thus, the specification does not otherwise limit this claim language.		
2	Term 2. . . wherein the agent comprises a therapeutically effective amount of an extract obtained from . . .	<p>therapeutically effective amount</p> <p><u>Proposed Construction:</u> "An amount or dose of an agent that when administered to an organism will produce a desired effect."</p> <p><u>Dictionary / Treatise Definitions:</u> WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (Phillip Babcock Gove, Ph.D. ed., 1993)</p> <p>therapeutic: "of or related to the treatment of disease or disorders by remedial agents or methods"; synonyms are "curative" and "medicinal."</p> <p><u>Intrinsic Evidence:</u> The opening sentence of the '570 Patent abstract states that the invention relates to compositions and methods for <i>treating</i> Alzheimer's disease. '570 Patent Abstract (emphasis added).</p> <p>The specification provides a wide list of both human and animal ailments caused by amyloids which may be treated with the patented composition. "The amyloid disease for treatment with the pharmacological agent is selected from the group consisting of the amyloid associated with Alzheimer's disease, Down's syndrome and hereditary cerebral hemorrhage with amyloidosis of the Dutch type (wherein the specific amyloid is referred to as beta-amyloid protein or A. beta.), the amyloid associated with chronic inflammation, various forms of malignancy and Familial Mediterranean Fever (wherein the specific amyloid is referred to as AA amyloid or inflammation-associated amyloidosis), the amyloid associated with multiple myeloma and other B-cell dyscrasias (wherein the specific amyloid is referred to as AL amyloid), the amyloid associated</p>	<p>therapeutically effective amount</p> <p><u>Proposed Construction:</u> "An amount or dose of a pharmaceutical agent that when administered to a person who has therapeutic need, will produce a specifically desired physiological effect."</p> <p><u>Dictionary/Treatise Definitions:</u> WEBSTER'S NINTH NEW COLLEGiate DICTIONARY (Frederick C. Mish, ed., 1986)</p> <p>therapeutic: "of or relating to the treatment of disease or disorders by remedial agents or methods"</p> <p>effective: "producing a decided, decisive, or desired effect"</p> <p><u>Intrinsic Evidence:</u> "A pharmaceutical agent for treating an amyloid disease . . ." Abstract.</p> <p>The specification addresses dosages determined by physicians. Physicians treat humans. Further, the patent is directed at treatment of subjects with amyloidoses. "However, it will be understood that the therapeutic dosage administered will be determined by the physician in the light of the relevant circumstances including the clinical condition to be treated, the organ or tissues affected or</p>

JOINT CLAIM CONSTRUCTION CHARTS
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	<p>with type II diabetes (wherein the specific amyloid is referred to as amylin or islet amyloid), the amyloid associated with the prion diseases including Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, kuru and animal scrapie (wherein the specific amyloid is referred to as PrP amyloid), the amyloid associated with long-term hemodialysis and carpal tunnel syndrome (wherein the specific amyloid is referred to as beta.₂-microglobulin amyloid), the amyloid associated with senile cardiac amyloid and Familial Amyloidotic Polyneuropathy (wherein the specific amyloid is referred to as trasthyretin or prealbumin), and the amyloid associated with endocrine tumors such as medullary carcinoma of the thyroid (wherein the specific amyloid is referred to as various of procalcitonin).” ‘570 Patent col. 7:65.</p> <p>The specification supports a construction that includes subjects other than humans in another section as well. “In the methods of the invention, amyloid formation, deposition, accumulation and/or persistence in a subject is inhibited by administering Uncaria tomentosa (or its active ingredients) in a therapeutic dosage to the subject. <i>The term subject is intended to include living organisms in which amyloidosis can occur. Examples of subjects include humans, monkeys, cows, dogs, sheep, cats, mice, rats, and transgenic species thereof.</i> ‘570 Patent col. 30:25 (emphasis added).</p> <p>The specification also supports a construction that includes psychological effects as well as physiological effects. “Alzheimer’s disease is a leading cause of dementia in the elderly, affecting 5-10% of the population over the age of 65 years [citation omitted]. In Alzheimer’s disease, the parts of the brain essential for cognitive process such as memory, attention, language, and reasoning degenerate, robbing victims of much that makes us human, including independence. ‘570 Patent col. 13:25 (emphasis added).</p>	<p>suspended to be affected with amyloid accumulation, and the chosen route of administration.” Col. 28, ll. 36-41. “Use of extracts from the inner bark and root parts of Uncaria tomentosa, and use of the ingredients contained within the various commercial preparations of Uncaria tomentosa, <i>benefit human patients with Alzheimer’s disease and other amyloidoses</i> due to Uncaria tomentosa’s newly discovered ability to inhibit amyloid fibril formation, inhibit amyloid fibril growth, inhibit amyloid-proteoglycan interactions, inhibit amyloid-glycosaminoglycan interactions, and cause dissolution and/or disruption of preformed amyloid fibrils.” Col. 32, ll. 13-22 (emphasis added). “[T]he invention is the only system that effectively provides for use of extracts from the inner bark and root parts of Uncaria tomentosa, and use of the ingredients contained within the various commercial preparations of Uncaria tomentosa, <i>to benefit human patients with Alzheimer’s disease and other amyloidoses . . .</i>” Col. 5, ll. 17-22 (emphasis added). “In the methods of the invention, <i>amyloid formation, deposition, accumulation and/or persistence in a subject</i> is inhibited by administering Uncaria tomentosa (or its active ingredients) in a therapeutic dosage to the subject.” Col. 30, ll. 22-25 (emphasis added).</p> <p>The patent is directed at</p>
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JOINT CLAIM CONSTRUCTION CHARTS (CV6-1297Z) — 9

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		<p>treating amyloid deposits, a physiological condition. “Amyloid is a generic term referring to a group of diverse, but specific extracellular protein deposits . . .” Col. 11, ll. 52-53. “Alzheimer's disease is characterized by the deposition and accumulation of a 39-43 amino acid peptide termed on the beta-amyloid protein . . .” Col. 14, ll. 12-14. “The pathological hallmarks of Alzheimer's disease is therefore the presence of ‘plaques’ and ‘tangles’, with amyloid being deposited in the central core of plaques. The other major type of lesion found in the Alzheimer's disease brain is the accumulation of amyloid in the walls of blood vessels, both within the brain parenchyma and in the walls of meningeal vessels which lie outside the brain.” Col. 14, ll. 34-40. The specification addresses only the physiological treatment of Alzheimer's and other amyloid diseases.</p> <p><u>Extrinsic Evidence:</u> Expert Report of Steven Kern.</p>
Term 3. . . . wherein the agent comprises a therapeutically effective amount of an extract obtained from . . .	extract <u>Proposed Construction:</u> “Something separated or otherwise obtained (as constituent elements or juices) from a substance, such as, by treating with a solvent (as alcohol), distilling, evaporating, subjecting to pressure or centrifugal force, or by some	Agreed.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27	<p>numbers 1, 8, 9, and 14.</p> <p>chemical, mechanical, or other extraction process.”</p> <p><u>Dictionary / Treatise Definitions:</u> WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (Phillip Babcock Gove, Ph.D. ed., 1993)</p> <p>extract (as a noun): “something extracted”</p> <p>extract (as a verb): “to separate or otherwise obtain (as constituent elements or juices) from a substance by treating with a solvent (as alcohol), distilling, evaporating, subjecting to pressure or centrifugal force, or by some other chemical or mechanical process.”</p> <p><u>Intrinsic Evidence:</u> The specification states that “the pharmacological agent is preferably an extract obtained from Uncaria tomentosa, the extract being derived from the inner bark or root tissue in Uncaria tomentosa, and advantageously taken from some commercially available source, such as pills, tablets, caplets, soft and hard gelatin capsules, lozenges, sachets, cachets, vegicaps, liquid drops, elixers, suspensions, emulsions, solutions, syrups, tea bags, aerosols (as a solid or in a liquid medium), suppositories, sterile injectable solutions, sterile packaged powders, bark bundles or bark powder.” ‘570 Patent col. 7:15. In the quoted passage, “extract” refers to the substance separated from the inner bark or root tissue of the plant by others who then offer it in various forms for commercial sale.</p> <p>As described further in the ‘570 Patent, these commercial “extracts” can be further processed to create new “extracts.” The specification states “In one such method, an extract prepared from commercially obtained pills, tablets, . . . bark bundles and/or bark powder, using the method employing some or all of the following steps: a) extraction from Uncaria tomentosa regardless of form as described above using an organic solvent</p>	
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1	such as propanol, b) concentration of the extract by using a method such as rotary evaporation, lyophilization or precipitation, . . .” ‘570 Patent col. 6:40 (emphasis added).	
2	Term 4. . . an extract obtained from the inner bark of cat’s claw . . . Found in claims 1 and 9.	inner bark <u>Proposed Construction:</u> “That portion of the bark that lies closest to the center of the plant.” <u>Dictionary / Treatise Definitions:</u> WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (Phillip Babcock Gove, Ph.D. ed., 1993) inner: “situated farther in <an inner chamber> <the inner bark>” bark: “the exterior dead cellular covering of woody roots and stems . . .”
3	Term 5. . . wherein the commercially available source of Uncaria tomentosa is selected from . . .	commercially available source <u>Proposed Construction:</u> “A supply from which something may be secured, directly or indirectly, by purchase.” <u>Intrinsic Evidence:</u> This definition of the term is exemplified by the language of claim 3, which lists no less than twenty-two examples of commercially available sources. ‘570 Patent claim 3.
4	Term 6. . . . wherein the therapeutically effective amount of extract has an in vitro amyloid inhibitory activity or efficacy greater than 50%. Found in claims 8 and 14.	amyloid inhibitory activity or efficacy <u>Proposed Construction:</u> “Having the effect of reducing, suppressing, retarding, eliminating, preventing, inhibiting, interfering with, disrupting, and/or dissolving amyloid fibril or amyloid protein deposits.” <u>Dictionary / Treatise Definitions:</u> WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY, UNABRIDGED (Phillip Babcock Gove, Ph.D. ed., 1993)

JOINT CLAIM CONSTRUCTION CHARTS
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	<p>1 inhibitory: "tending or serving to inhibit"</p> <p>2 inhibit: "to reduce or suppress the activity of; to retard or prevent the formation of; to retard, interfere with, or prevent (a chemical process or reaction)"</p> <p>3</p> <p>4 efficacy: "the power to produce an effect"</p> <p>5</p> <p>6 <u>Intrinsic Evidence:</u></p> <p>7 The phrase relates to a measurement of the 8 effectiveness of <i>Uncaria tomentosa</i> 9 extract in inhibiting the formation or 10 growth of amyloid deposits in laboratory 11 test specimens. The efficacy of a 12 substance in inhibiting amyloid formation 13 can be measured through controlled 14 bioassays. Some of these tests utilize 15 Thioflavin T fluorometry. Thioflavin T is 16 known to bind to fibrillar amyloid 17 proteins, and an increase in fluorescence 18 correlates with an increase in amyloid fibril formation, whereas a decrease in fluorescence correlates with a decrease in amyloid fibril formation. '570 Patent col. 17:5. In these tests, the effectiveness of the compound can be quantified by a reduction in fluorescence from the control group. For example, Figure 1 shows that after one week, the candidate labeled PTI- 00700 reduced the fluorescence of Thioflavin T by 78% compared to the control group labeled AB. '570 Patent col. 18:30 and Figure 1.</p> <p>19</p> <p>20</p> <p>21</p> <p>22 (This space left blank intentionally)</p> <p>23</p> <p>24</p> <p>25</p> <p>26</p> <p>27</p>	
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1 The specification also describes the effect
2 of the patented composition. "All of these
3 studies suggest that providing a drug to
4 reduce, eliminate or prevent fibrillar A.
beta. formation, deposition, accumulation
and/or persistence in the brains of human
patients is believed to serve as an effective
therapeutic. '570 Patent col. 15:15.

6 DATED this 4th day of May, 2007.

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CERTIFICATE OF SERVICE

I hereby certify that on the 4th day of May, 2007, I served a true and correct copy
of the following document by the method indicated below and addressed as follows:

Joint Claim Chart

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DATED this 4th day of May, 2007.

s/ Michelle Webb
Michelle Webb